REMARKS

This Amendment is responsive to the Office Action dated August 5, 2008. Applicant has amended claims 1, 6, 7, 9, 10, 12 and 35, and canceled claim 3. Claims 1, 4–10, 12–22, 28–31, and 33–35 are pending.

In view of the above amendments and the following remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections set forth in the Office Action dated August 5, 2008.

Amendments to the Specification

In response to the request for Applicant to update the references to commonly owned patent applications, Applicant has amended previously amended paragraphs [0002] and [0051]. The amended paragraphs correctly reflect the status of the referenced patents and patent applications.

Claim Rejection Under 35 U.S.C. § 103(a)

In the Office Action, claims 1, 3–10, 12–22, 28–31 and 33–35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Faltys et al. (U.S. Patent No. 6,308,101, hereafter "Faltys") in view of Probst et al. (U.S. Patent Application Publication No. 2003/0017372, hereafter "Probst"). In addition, the Office Action cited Trabucco et al. (U.S. Patent No. 5,243,977, hereafter "Trabucco"), Sanchez-Zambrano (U.S. Patent No. 5,895,414, hereafter "Sanchez-Zambrano"), Gray (WO 92/20402, hereafter "Gray"), and Bardy et al. (U.S. Patent Application Publication No. 2002/0042634, hereafter "Bardy") as evidence of conventional features in the art.

Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested modification to arrive at the claimed inventions.

For example, with reference to independent claims 1, 30, and 35, the applied references lack any teaching that would have suggested an implantable medical device including, in part, a plurality of interconnected modules, at least one of the modules comprising a metallic housing,

and a flexible overmold that at least partially encapsulates each of the interconnected modules. As claims 1, 30, and 35 further recite, the flexible overmold is formed such that a surface of the flexible overmold is concave along two perpendicular axes prior to manipulation of the implantable medical device, and is adapted to be implanted proximate to a cranium of the patient.

The Examiner recognized that Faltys fails to teach or suggest that encasing mold 174, which encases a coil 172, of Faltys is concave along at least two axes prior to manipulation of the IMD and adapted to be implanted proximate to a cranium of a patient.[1] The Examiner characterized Probst as teaching a housing of IMD 10 that includes a "first surface [that] is concave along multiple axes"[2] and is adapted to be implanted proximate to a cranium.[3] The Examiner admitted that Faltys in view of Probst does not teach that the first surface is concave along two perpendicular axes, but stated that it was "well known in the art of implanted devices for an outer surface of a device to be concave along at least two perpendicular axes." In support of this statement, the Examiner cited Trabucco, Sanchez-Zambrano, and Bardy.[4]

Initially, Applicant maintains that mold 174, as illustrated in FIGS. 3A and 3B of Faltys, does not at least partially encapsulate a plurality of modules, as required by Applicant's claims, at least under any reasonable interpretation of the term "encapsulate." As illustrated in FIGS. 3A and 3B of Faltys, a single surface of mold 174 simply contacts a single surface of each of SP/OWR unit 162 and ICS 112', and does not at least partially encapsulate either of SP/OWR unit 162 or ICS 112' under any reasonable interpretation of the term "encapsulate." By way of analogy, a sheet of paper on top of a desk does not even partially encapsulate the desk, nor does a sheet of paper on top of another sheet of paper partially encapsulate the other sheet of paper. Similarly, mold 174 merely disposed on top of SP/OWR unit 162 and ICS 112', as illustrated in FIGS. 3A and 3B of Faltys, does not even partially encapsulate SP/OWR unit 162 and ICS 112'. One of ordinary skill in the art would not have considered mold 174 to partially encapsulate SP/OWR unit 162 and ICS 112', even under the broadest reasonable interpretation of the term "partially encapsulate." One of ordinary skill in the art would consider the Examiner's interpretation of the term "partially encapsulate" to be unreasonably broad.

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[1] Office Action dated August 5, 2008, page 4, lines 7–10.
[2] *Id.* at page 4, lines 17 and 18.
[3] *Id.* at page 4, lines 19–23.
[4] Office Action dated August 5, 2008, page 5, lines 3–13.

The other applied references fail to teach or suggest a flexible overmold that at least partially encapsulates each of a plurality of interconnected modules, at least one or which includes a metallic housing. Probst and Sanchez-Zambrano fail to even suggest a flexible overmold. Probst fails to disclose an overmold, and discloses that the housing of the device is metallic. Sanchez-Zambrano fails to disclose an overmold, and also fails to provide any detail regarding the material that forms the housing.

Similarly, Bardy also fails to disclose or suggest a flexible overmold that at least partially encapsulates a plurality of modules, at least one of which comprises a metallic housing. Bardy discloses that the canister (e.g., housing) of the device may be malleable or may be metallic, but does not disclose that the canister encloses a plurality of modules, one of which comprises a metallic housing.

Finally, Gray also fails to disclose or suggest a flexible overmold that at least partially encapsulates a plurality of modules, at least one of which comprises a metallic housing. Gray discloses two distinct embodiments, one that includes a resilient plastic or metallic container 10, and a second that includes a flexible cup-shaped container 18. In either embodiment, the container directly encloses the pulse generator circuitry, and does not include a module including a metallic housing.

Therefore, Applicant submits that none of applied references teaches or suggest a flexible overmold that at least partially encapsulates each of a plurality of interconnected modules, at least one or which includes a metallic housing, as required by Applicant's independent claims, as amended. There is no rational reason for a person of ordinary skill in the art to have modified mold 174 to at least partially encapsulate SP/OWR unit 162 and ICS 112'. Moreover, there is no rational reason for a person of ordinary skill in the art to have further modified mold 174 to meet the other requirements of Applicant's amended independent claims. In particular, even if it were well known for an outer surface of a medical device to be concave along at least two perpendicular axes, as suggested by the Examiner, one of ordinary skill in the art would have seen no rational reason to modify mold 174 in order to meet the requirements of Applicant's claims.

Mold 174 is not adapted to be implanted proximate to a cranium. Instead, FIG. 3A illustrates that mold 174 is implanted proximate to skin 110, and that SP/OWR unit 162 and ICS 112' are located between mold 174 and a cranium of a patient. Thus, mold 174 does not include a surface adapted to be implanted proximate a cranium of a patient. Instead, the surface of mold 174 nearest the cranium when IMD 160 is implanted contacts the flat surfaces of the housings of modules 162 and 112'. Because mold 174 contacts the flat surfaces of the housings of modules 162 and 112', one of ordinary skill in the art would have had no rational reason to modify mold 174 to be concave in the manner recited in Applicant's claims.

The Examiner asserted that the other applied references contain teachings that would have motivated one of ordinary skill in the art to modify mold 174 of the Faltys device to include a surface that is concave along two perpendicular axes. However, Applicant respectfully disagrees. Instead, Applicant submits that assuming, *arguendo,* the references would have provided any motivation to modify the Faltys device, one of ordinary skill would have been motivated to modify the device in one of two ways. Neither of these modifications would have resulted in a device that would render Applicant's claimed inventions unpatentable.

In the first case, one of ordinary skill in the art may have been motivated to modify a surface of SP/OWR unit 162 and/or ICS 112' to be concave in one or more axes. In each of the applied references, the surface that is concave, whether it is in one or two axes, is the surface which contacts tissue of a patient. Accordingly, even if one of ordinary skill in the art would have had motivation to modify the Faltys device in view of the cited references, the modification suggested by the applied references would be, at best, to modify the surfaces of SP/OWR unit 162 and ICS 112' that are proximate the cranium of the patient to be concave along one or more axes. That is, the applied references in no way would have suggested modifying the mold 174 of Faltys device to include a surface that is concave along two perpendicular axes, because the surface of mold 174 nearest to the cranium contacts SP/OWR unit 162 and ICS 112', not the cranium or other tissue.

Alternatively, even if one of ordinary skill were motivated to modify mold 174 to include a surface that is concave along two perpendicular axes, this surface would not be adapted to be implanted proximate to the cranium of a patient. As described above, FIG. 3A of Faltys illustrates one surface of mold 174 is proximate to skin 110 and a second surface of mold 174

contacts SP/OWR unit 162 and ICS 112'. Accordingly, neither modifying mold 174 to include a surface that is concave along two perpendicular axes or modifying the surface of proximity system 160 of Faltys that is proximate to the cranium (e.g., surfaces of SP/OWR unit 162 and ICS 112') would result in a device that includes a flexible overmold that is formed such that a surface of the flexible overmold is concave along two perpendicular axes prior to manipulation of the implantable medical device and is adapted to be implanted proximate to a cranium of the patient, where the flexible overmold at least partially encapsulates a plurality of modules, at least one of which comprises a metallic housing, as is required by Applicant's claims 1, 30, and 35.

Claims 4–10, 12–22, 28, and 29 depend from claim 1, and claims 31, 33, and 34 depend from claim 30. Accordingly, all pending claims are in condition for allowance for at least the reasons presented above. For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 1, 4–10, 12–22, 28–31, and 33–35 under 35 U.S.C. 103(a). Withdrawal of this rejection is respectfully requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

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By:

Name: Jason D. Kelly
Reg. No.: 54,213

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.286.8350
Facsimile: 651.735.1102